

Brand Name	Generic Name	Indications	Route of Administration	Action
Aciphex	rabeprazole	Healing/Maintenance of Erosive or Ulcerative GERD, Treatment of symptomatic GERD, Healing of duodenal ulcers, H. Pylori eradication, Hypersecretory conditions, such as Zollinger-Ellison syndrome	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.
Anbesol, Orabase, Orajel, Baby Orajel, Hurracaine, Topex, etc.	Oral OTC Benzocaine Products	Oral Pain	Oral	Over-the-counter (OTC) benzocaine products should not be used to treat infants and children < 2 years of age. The FDA is also warning that these products should only be used in adults and children ≥ 2 years of age if they contain certain warnings on the drug label. <b>Benzocaine products carry serious risks and provide little to no benefits for treating oral pain, including sore gums in infants due to teething. Benzocaine can cause methemoglobinemia, a condition in which the amount of oxygen carried through the blood is greatly reduced. This can be life-threatening and result in death.</b>
Dexilant	dexlansoprazole	GERD, Erosive Esophagitis, Heartburn	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.

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Juluca	dolutegravir/rilpivirine	HIV-1 Infection	Oral	Serious cases of <b>neural tube birth defects have been reported in babies born to women treated with dolutegravir</b> . Neural tube defects are birth defects that can occur early in pregnancy, when the spinal cord, brain and related structures do not form properly. Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.
Keytruda	pembrolizumab	Melanoma, Non-small cell lung cancer, Head and Neck cancer, Hodgkin Lymphoma, Primary Mediastinal Large B-Cell Lymphoma, Urothelial Carcinoma, Microsatellite Instability-High Cancer, Gastric Cancer, Cervical Cancer	IV	<b>Decreased survival is associated with the use of Keytruda (pembrolizumab) as monotherapy</b> to treat patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1 (PD-L1).

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Lamictal	lamotrigine	Epilepsy, Bipolar Disorder	Oral	Lamictal can cause a <b>rare but very serious reaction that excessively activates the body's infection-fighting immune system</b> . This can cause severe inflammation throughout the body and lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly. The immune system reaction, called <b>hemophagocytic lymphohistiocytosis (HLH)</b> , causes an uncontrolled response by the immune system. HLH typically presents as a persistent fever, usually greater than 101°F, and it can lead to severe problems with blood cells and organs throughout the body such as the liver, kidneys, and lungs.
Lenvima	lenvatinib	Differentiated Thyroid Cancer, Renal Cell Cancer	Oral	<b>Wound healing complications, including fistula formation and wound dehiscence</b> , can occur with Lenvima. Lenvima should be withheld for at least 6 days prior to scheduled surgery. Lenvima may be resumed after surgery based on clinical judgment of adequate wound healing. Lenvima should be permanently discontinued in patients with wound healing complications.
Neulasta	pegfilgrastim	Decrease the incidence of infection in patients with non-myeloid malignancies, Increase survival in patients exposed to myelosuppressive doses of radiation	Sub-Q	<b>Aortitis</b> has been reported in patients receiving Neupogen or Neulasta. It may occur as early as the first week after start of therapy. Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (eg, C-reactive protein and white blood cell count). Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue Neupogen or Neulasta if aortitis is suspected.

Brand Name	Generic Name	Indications	Route of Administration	Action
Neupogen	filgrastim	Decrease the incidence of infection in patients with non-myeloid malignancies, Reduce the time to neutrophil recovery and duration of fever following chemotherapy in patients with myeloid leukemia, Reduce the duration of neutropenia, Mobilize hematopoietic progenitor cells for collection by leukapheresis, Increase survival in patients exposed to myelosuppressive doses of radiation	Sub-Q	<b>Aortitis</b> has been reported in patients receiving Neupogen or Neulasta. It may occur as early as the first week after start of therapy. Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (eg, C-reactive protein and white blood cell count). Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue Neupogen or Neulasta if aortitis is suspected.
Nexium	esomeprazole strontium	GERD, Reduce risk of NSAID-associated gastric ulcer, H. Pylori eradication, Hypersecretory conditions, such as Zollinger-Ellison	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.

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Prevacid	lansoprazole	Duodenal ulcer treatment/maintenance, H. Pylori eradication, Treatment of active benign gastric ulcer, Healing/Risk reduction of NSAID-associated gastric ulcer, GERD, Erosive Esophagitis, Hypersecretory conditions, such as Zollinger-Ellison syndrome	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.
Prilosec	omeprazole	Duodenal ulcer treatment, H. Pylori eradication, Treatment of active benign gastric ulcer, GERD, Erosive Esophagitis, Hypersecretory conditions, such as Zollinger-Ellison syndrome	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.

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Protonix	pantoprazole	Short-term treatment of Erosive Esophagitis associated with GERD, Healing/maintenance in Erosive Esophagitis, Hypersecretory conditions, such as Zollinger-Ellison syndrome	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.
Remodulin	treprostinil	Pulmonary Arterial Hyp	Sub-Q, IV	Remodulin is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with Remodulin may produce <b>symptomatic hypotension</b> . Remodulin inhibits platelet aggregation and <b>increases the risk of bleeding</b> .
Samsca	tolvaptan	Clinically significant hypervolemic and euvolemic hyponatremia	Oral	Samsca can cause <b>serious and potentially fatal liver injury</b> and should not be prescribed or used outside of the FDA-approved REMS for ADPKD (autosomal dominant polycystic kidney disease) patients.
Stelara	ustekinumab	Plaque Psoriasis, Psoriatic Arthritis, Crohn's Disease	Sub-Q, IV	Cases of <b>interstitial pneumonia, eosinophilic pneumonia and cryptogenic organizing pneumonia</b> have been reported during post-approval use of Stelara. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. Patients improved with discontinuation of therapy and in certain cases administration of corticosteroids. If diagnosis is confirmed, discontinue Stelara and institute appropriate treatment.
Tecentriq	atezolizumab	Locally Advanced or Metastatic Urothelial Carcinoma, Metastatic Non-Small Cell Lung Cancer	IV	<b>Decreased survival is associated with the use of Tecentriq (atezolizumab) as monotherapy</b> to treat patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1 (PD-L1).

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Tivicay	dolutegravir	HIV-1 Infection	Oral	Serious cases of <b>neural tube birth defects have been reported in babies born to women treated with dolutegravir</b> . Neural tube defects are birth defects that can occur early in pregnancy, when the spinal cord, brain and related structures do not form properly. Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.
Triumeq	abacavir/dolutegravir	HIV-1 Infection	Oral	Serious cases of <b>neural tube birth defects have been reported in babies born to women treated with dolutegravir</b> . Neural tube defects are birth defects that can occur early in pregnancy, when the spinal cord, brain and related structures do not form properly. Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.
Viberzi	eluxadolone	Irritable bowel syndrome with diarrhea	Oral	<b>Constipation, sometimes requiring hospitalization, has been reported following Viberzi administration.</b> In postmarketing experience, severe cases with development of intestinal obstruction, intestinal perforation, and fecal impaction, requiring intervention, have also been reported. Patients should be instructed to stop Viberzi and immediately contact their healthcare provider if they experience severe constipation. Viberzi use should be avoided with other drugs that may cause constipation.

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Vimovo	esomeprazole/naproxen	Naproxen component: Osteoarthritis, RA, Ankylosing Spondylitis; Esomeprazole component: to reduce the risk of developing naproxen-associated gastric ulcers	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.
Yosprala	omeprazole/aspirin	Aspirin component: Reduce risk of death/non-fatal stroke or MI; Omeprazole component: to reduce the risk of developing aspirin-associated gastric ulcers	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.
Zegerid	omeprazole/sodium bicarbonate	Short-term treatment of active duodenal ulcer and active benign gastric ulcer, GERD, Erosive Esophagitis, Reduction of upper GI bleeding in critically ill patients	Oral	PPI use is associated with an <b>increased risk of fundic gland polyps</b> that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.